



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 21 2008

Afx, Inc.  
c/o Ms. Nancy Norris  
Program Director  
47929 Fremont Boulevard  
Fremont, CA 94538

Re: K013946

Trade/Device Name: FLEX 10 Accessory for the Afix Microwave Ablation System  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical unit and accessories  
Regulatory Class: II (two)  
Product Code: OCL, NEY  
Dated: November 28, 2001  
Received: November 29, 2001

Dear Ms. Norris:

This letter corrects our substantially equivalent letter of February 27, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

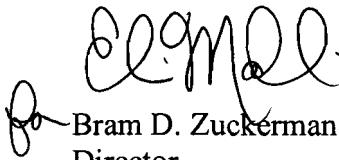
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.

Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

AFx inc.

**FLEX 10 Ablation Probe Accessory**  
**Premarket Notification 510(k)**

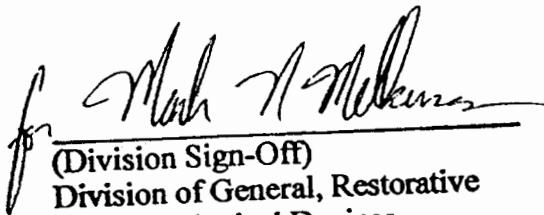
**INDICATIONS FOR USE STATEMENT**

510(k) Number (if known): K 013946

Device Name: FLEX 10 Ablation Probe Accessory for the  
AFx Microwave Ablation System

**Indications for Use**

The FLEX 10 Accessory is intended to be used with the AFx Microwave Ablation System for the surgical ablation of soft tissue, in addition to striated, cardiac and smooth muscles. The system is designed to ablate tissue by the induction of thermal necrosis in the targeted tissues.

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K013946

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(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(i)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR  
(Per 21 CFR 801.109)

Over-the-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

**SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**K 013 946

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 8807.92

**Contact Person**

Nancy Norris  
Program Manager  
AFx inc.  
47929 Fremont Blvd  
Fremont, CA 94538  
(510) 651-7430  
(510) 651-7061 fax

**FEB 27 2002****Device Name**

Trade Name: FLEX 10 Accessory for the AFx Microwave Ablation System

Common Name: None

Classification Name: Cryosurgical unit and accessories (21 CFR 878.4350);

**Predicate Devices**

AFx Microwave Ablation System and Accessories K003978

CryoGen Cardiac Cryosurgery System K974320

Heartport Maze System: Cryoprobe Set K970496

**Device Description**

The FLEX 10 Accessory is a surgical ablation probe that directs the microwave energy developed by the AFx Microwave Generator into the target tissue. The FLEX 10 Accessory is a sterile, hand-held, single-use, surgical ablation device. The ablative microwave energy emanates from an antenna contained in the ablation sheath at the distal end of the device.

The FLEX 10 Accessory has a flexible 2 m long insulated coax cable that attaches the Probe to the Microwave Generator output cable. The flexible cable is attached to a 24 cm long hand grip, followed by a 15 cm section of stainless steel hypotube, followed by a highly flexible PTFE ablation sheath, which contains the movable microwave energy delivery antenna. The end of the ablation sheath is attached to a PEBAK positioning sheath and sutures to aid in the proper placement of the ablating sheath. Moving the sliding ring on the hand grip moves the antenna to discrete numbered locations in the ablating sheath. The position of the antenna within the ablating sheath is displayed to the user by the position indicator of the sliding ring on the hand grip.

**Indications for Use**

The FLEX 10 Accessory is intended to be used with the AFx Microwave Ablation System for the surgical ablation of soft tissue, in addition to striated, cardiac and smooth muscles. The system is designed to ablate tissue by the induction of thermal necrosis in the targeted tissues.

**510(k) Summary – continued****Testing in Support of Substantial Equivalence Determination**

The results of bench testing and biocompatibility testing support the substantial equivalence claims of the FLEX 10 Accessory for the AFx Microwave Ablation System in the above indication. The animal testing demonstrated the reliability of the sliding antenna concept.

**Substantial Equivalence Conclusion**

Substantial equivalence is based on the fact that the FLEX 10 Accessory for the AFx Microwave Ablation System has equivalent data-based intended uses as the predicate AFx Microwave Ablation System with its LYNX and FLEX Ablation Probe Accessories. There are no significant technological differences between the FLEX 10 and cleared microwave ablation probes. There are no new questions of safety or efficacy raised by the AFx Microwave Ablation System with any of its ablation probes vis-à-vis the predicate cryogenic ablation devices. Therefore, it can be concluded that the FLEX 10 Ablation Probe Accessory for the AFx Microwave Ablation System is substantially equivalent to the predicate devices.